IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC., Plaintiff, v. NEOGENOMICS LABORATORIES, INC., Defendant.	C.A. No. 1:23-CV-629

DEFENDANT NEOGENOMICS LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO MODIFY AND/OR CLARIFY

FILED UNDER SEAL
[EXPEDITED TREATMENT REQUESTED]

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I. MOTION TO MODIFY OR CLARIFY

NeoGenomics Laboratories, Inc. ("NeoGenomics") respectfully requests modifications and/or clarifications of this Court's preliminary injunction order (of December 27, 2023) to eliminate legal over-breadth, impose the required security and add specificity. NeoGenomics requests expedited treatment of this motion given the immediate harm and a response to this motion by January 2, 2024.

First, the injunction should be modified to clarify that NeoGenomics is enjoined only from the infringing use or inducing infringing use of the '035 Patent in the United States. A method patent, like the '035 Patent, is directly infringed by actual use, not merely by sales or manufacture of a test. The injunction, however, improperly treats the '035 Patent as though it were a product patent. In addition to prohibiting the use of the patented method, it improperly prohibits NeoGenomics from making, selling, or offering to sell RaDaR. This is overbroad because it enjoins activity that is not unlawful. For example, even if the actual use of the steps of the RaDaR test (and thus the alleged infringement of the '035 Patent) lawfully occurs outside of the United States, the current form of the injunction would appear to prevent legitimate activity by preventing the making of the components, and selling, or offering to sell such testing. The injunction should be limited to prohibiting the actual "use" of the RaDaR to amplify and sequence cfDNA test in the United States and the promotion of such "uses" in the United States of the RaDaR test.

Second, the injunction should be modified to require Natera to post security. Rule 65(c) *requires* a court to assess whether and in what amount security is necessary before

issuance of a preliminary injunction. Such security should be based on the likely injury to the restrained party if the injunction ultimately is determined to have been entered in error. And here, the evidence shows that NeoGenomics faces injury of approximately $400 million or more from the preliminary injunction. NeoGenomics thus requests that the injunction be modified to require Natera to post security in the amount of $400 million.

Third, NeoGenomics seeks clarification regarding the permissible uses of RaDaR for existing clinical testing, scientific reporting, and planned pharmaceutical research.

A. The Injunction Is Overbroad

The injunction is overbroad as a legal matter in that it prohibits NeoGenomics from "making, using, selling, or offering for sale in the United States" RaDaR or any assay not colorably different from RaDaR, and from "promoting, advertising, marketing, servicing, distributing, or supplying" RaDaR "so as to induce others' infringement." D.I. 171 ¶ 2. The '035 Patent is a method patent, because it "is a mode of treatment of certain materials to produce a given result." *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972) (quotation marks omitted). However, the "use of a patented method does not infringe unless each of the steps is performed within this country." *NTP, Inc. v. Rsch. In Motion*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) (quotation marks omitted), *abrogated in part on other grounds by Zoltek Corp. v. United States*, 672 F.3d 1309 (Fed. Cir. 2012) (en banc); *see also Acceleration Bay LLC v. Elec. Arts Inc.*, 2019 WL 1376036, at *5 (D. Del. Mar. 27, 2019); *Home Gambling Network, Inc. v. Piche*, 2013 WL 5492568, at *6 (D. Nev. Sept. 30, 2013). "Neither the Federal Circuit nor the Supreme Court has ever recognized that one may

infringe a method claim by selling or offering to sell a service that performs the method." *Wright's Well Control Servs., LLC v. Oceaneering Int'l, Inc.*, 2017 WL 3706344, at *3 (E.D. La. Aug. 28, 2017).

Under these principles, the Court cannot enjoin NeoGenomics from "making," "selling" or "offering" RaDaR in the United States—it can only enjoin NeoGenomics from actually *"using"* the patented process within the United States. Likewise, NeoGenomics can be enjoined from inducement of infringement through "promoting, advertising, marketing, servicing, distributing, or supplying" RaDaR so as "to induce others' infringement" only insofar as that is actual use in the United States. *See* 35 U.S.C. § 271(b) (indirect infringement requires third-party infringement in the United States). The injunction must therefore be modified to prohibit only the "use" of RaDaR to practice the patented process in the United States, and to prohibit only those marketing or advertising efforts that induce infringement via actual use of the '035 Patent in the United States. A proposed revised injunction accompanies this motion.

B. The Court Should Require Security

Under Federal Rule of Civil Procedure 65(c), "[t]he court may issue a preliminary injunction or a temporary restraining order *only* if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any part found to have been wrongfully enjoined or restrained." (emphasis added). Accordingly, "[a] district court *must* fix a bond whenever it grants a preliminary injunction or restraining order." *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 (4th Cir. 1999)

(emphasis added); *see also Pashby v. Delia*, 709 F.3d 307, 332 (4th Cir. 2013) (a court "cannot disregard the bond requirement altogether").

The security amount is determined by reference to "record evidence." *Fleet Feet, Inc. v. Nike Inc.*, 419 F. Supp. 3d 919, 949 (M.D.N.C. 2019). A court "usually will fix security in an amount that covers the potential incidental and consequential costs as well as either the losses the unjustly enjoined or restrained party will suffer during the period he is prohibited from engaging in certain activities." *Hoechst Diafoil*, 174 F.3d at 421 n.3 (quotation marks omitted); *see also Fleet Feet*, 419 F. Supp. 3d at 949 (similar). A court also should "consider the likelihood that the injunction was improperly issued." *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 2020 WL 2312030, at *7 (E.D. Va. May 8, 2020).

Here, the record shows that [redacted] By its current terms, the injunction prevents NeoGenomics from earning any return on that investment while the injunction remains in effect. The reaction of the market to the injunction offers a similar valuation of the magnitude of potential harm to NeoGenomics: NeoGenomics's market capitalization dropped approximately $475 million in the trading day following issuance of the injunction. Sikri Decl. ¶ 13. Accordingly, NeoGenomics requests that the Court modify the injunction to require Natera to post security of $400 million, reflecting the likely harm to NeoGenomics if the injunction is found to have been improperly entered.

C. Clarification Is Needed

NeoGenomics also seeks clarification of paragraph 3 of the injunction, which exempts from its scope the use of RaDaR "in support of research and development with other persons or entities on projects or studies that began before the entry of this injunction" or "for use in or support of clinical trials in process or already approved by an agency of the United States." D.I. 171 ¶ 3. The Court included these exemptions because "there are clinical trials and research projects, which depend on the use of RaDaR, in process or approved to begin," and that "[t]he public interest does not support enjoining these uses." D.I. 169 at 21. The Court further "agree[d] that avoiding disruption to ongoing treatment, research, and clinical studies is proper." *Id.* NeoGenomics seeks clarification as to the scope of these exemptions.

First, NeoGenomics currently has three contracts for clinical testing and use of RaDaR that have been signed by all relevant parties, but for which actual testing of samples has not yet begun. Sikri Decl. ¶ 3. These contracts present the same concerns outlined by the Court in the Order, namely, that enjoining NeoGenomics from completing those contracts would unduly disrupt the important clinical work of third parties, requiring them to either abandon the trial or start from scratch seeking a new partner. *Id.* All three of these contracts involve trials that have been approved by the applicable institutional review board, with NeoGenomics specifically named as supplying the assay. *Id.* Cancellation of these contracts would be costly. *Id.* Additionally, the evidence shows that the higher sensitivity of RaDaR makes it the only viable option for some pharmaceutical companies,

D.I. ¶¶ 29–39, 43, meaning that NeoGenomics's execution of these contracts is unlikely to divert any business from Natera. NeoGenomics requests clarification that the injunction does not prohibit its performance under those contracts.

Second, NeoGenomics has another four contracts for clinical testing and use of RaDaR that are well into the drafting and negotiation stage, but which have not yet actually been signed by the parties. Sikri Decl. ¶ 4. In each case, the client has selected NeoGenomics as its preferred vendor, but the parties have not yet finalized the precise terms of the contract. *Id.* Aside from the legal distinction that there is no executed contract, these projects are not in a materially different state than the three executed contracts noted above. *Id.* Cancellation of these projects would be costly to both the pharmaceutical companies and patients, as would be starting over from scratch with a different assay. *Id.* And again, there is no probability that Natera would earn these contracts if NeoGenomics did not—and if Natera did earn those contracts, it would do so with a less sensitive assay, potentially impacting the efficacy of the trials. NeoGenomics thus likewise requests clarification that it may proceed with negotiation, execution, and performance of those contracts.

Finally, NeoGenomics wishes to advise the Court that a small number (<100) of patient blood samples were taken prior to the issuance of the injunction and are still in the process of being delivered to NeoGenomics for testing. Sikri Decl. ¶ 10. Those samples all have arrived and can be tested within the next month and are likely less than 100. *Id.* The samples cannot be diverted to a different provider, because blood samples deteriorate

quickly and it is imperative that NeoGenomics process them immediately, or else patients will suffer unnecessary delays in treatment. *Id.* ¶ 9. NeoGenomics believes that this testing falls within the exemption under paragraph 3 for continued use of RaDaR "for those patients already using it before the entry of this injunction," but is advising the Court of this use for transparency.

NeoGenomics also intends to engage in scientific reporting in publications and conferences regarding RaDaR. Several abstracts that present clinical research, updated analysis and longitudinal monitoring of cancer patients utilizing the RaDaR assay have been accepted and are scheduled to be presented at upcoming scientific conferences, including by third-party authors, such as the American Association for Cancer Research Annual Meeting, which will take place April 5-10, 2024 in San Diego, CA. In addition, clinical research and analyses utilizing the RaDaR assay have been submitted to scientific journals or are pending submission to scientific journals. *See* Sikri Decl. ¶ 7. Continued scientific reporting regarding RaDaR is an important component of allowing for innovation in the field of cancer detection, and it thus benefits patients and the public more generally to continue to research and discuss the RaDaR assay. NeoGenomics does not understand the injunction to prevent scientific reporting in publications and at conferences.

II. CONCLUSION

For the foregoing reasons, NeoGenomics respectfully requests that the Court modify the injunction to clarify that it does not reach lawful use of the patented method outside of the United States, modify the injunction to require Natera to post security in the amount of

$400 million, and clarify that NeoGenomics may proceed with the clinical trials and testing described above.

This the 29th day of December, 2023,

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CERTIFICATE OF WORD COUNT

The undersigned counsel hereby certifies that this brief complies with the word count limitations of Local Rule 7.3(d).

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CERTIFICATE OF SERVICE

I hereby certify that on December 29, 2023, I electronically filed the foregoing **DEFENDANT NEOGENOMICS LABORATORIES, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO MODIFY AND/OR CLARIFY** with the Clerk of Court using the CM/ECF system.

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